

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on August 17, 2004, and the documents cited therein.

Interview Summary

Applicants would like to thank Examiner Forman for the courtesy extended during the telephonic interview on May 4, 2004. Applicants' attorney Robin Chadwick participated in the interview with Examiner Forman.

The pending claims and cited art were discussed during the interview. No resolution of the outstanding issues was achieved.

In a second telephone conversation with Examiner Forman on or about September 17, 2004, Applicant's attorney Richard Schwartz clarified the objections and rejections relating to the priority claim of the application. Examiner Forman stated that the rejections relating to Lockhart et al., International Publication WO 97/27317 and Lockhart, U.S. Patent 6,344,316 were maintained because the priority claim was allegedly not properly made.

This account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicants respectfully request that the Examiner point out any deficiencies in his next communication so that Applicants can amend or supplement the interview summary.

Amendment to the Specification

Applicants have amended the specification to reflect the fact that the present application is a continuation-in-part of application serial number 08/882,649 filed June 25, 1997, now U.S. Patent 6,344,316, which is a continuation of PCT Application No. PCT/US97/01603 filed January 22, 1997, now International Publication WO 97/27317. Applicants submit that this claim of priority is properly made under 37 C.F.R. § 1.78(a)(5)(ii)(A) because the present application was filed prior to November 29, 2000 and each of the present inventors is a named inventor of both U.S. Patent 6,344,316 and PCT Publication WO 97/27317. Applicants have

also amended the specification to reflect the fact that the priority claim to U.S. Provisional Application No. 60/100,393 is made under 35 U.S.C. § 119(e).

Claims 1-19 are now pending in this application.

Objection to Specification Under 35 U.S.C. § 132

The Examiner has objected to the amendment to the specification filed May 28, 2004, wherein priority was claimed to application serial number 08/882,649 filed June 25, 1997, now U.S. Patent 6,344,316 and PCT Application No. PCT/US97/01603 filed January 22, 1997, now International Publication WO 97/27317. The amendment resulted in incorporation by reference of these documents by virtue of the amendment's juxtaposition to the existing phrase "the contents of which are hereby incorporated by reference." The Examiner stated that such an incorporation by reference represented new matter.

By virtue of Applicants' present amendment to the specification, the incorporation by reference phrase has been removed from the claim for § 120 benefit and has been placed in the statement of § 119(e) benefit, as originally filed. Withdrawal of the objection to the specification is respectfully requested.

Objection to Claim for Priority under § 120

The Examiner has objected to the amendment to the specification filed May 28, 2004, wherein priority was claimed to application serial number 08/882,649 filed June 25, 1997, now U.S. Patent 6,344,316 and PCT Application No. PCT/US97/01603 filed January 22, 1997, now International Publication WO 97/27317, because no relationship among these applications and the present application was included and further because the current status of the PCT application was not included.

Applicants' present amendment to the specification makes it clear that the present application is a continuation-in-part of application serial number 08/882,649 filed June 25, 1997, now U.S. Patent 6,344,316, which is a continuation of PCT Application No. PCT/US97/01603 filed January 22, 1997, now International Publication WO 97/27317. This amendment addresses the Examiner's objections. Withdrawal of the objection is respectfully requested.

Benefit of § 120 Priority for Claims 5, 11, 16, and 18

The Examiner has denied Applicants the benefit of their § 120 priority for claims 5, 11, 16, 18 because these claims allegedly are not adequately supported under 35 U.S.C. § 112 by parent U.S. patent 6,344,316 and grandparent International Publication WO 97/27317. Final Office Action at page 3. Reconsideration of this determination is respectfully requested.

Claims 5 and 16 are drawn to the method of claim 1 wherein the probes comprise single-stranded overhangs having free 3'-ends. The Examiner, as stated in the § 103(a) rejection at page 10 of the Final Office Action, is of the opinion that WO 97/27317 discloses overhangs having only free 5'-ends, as allegedly shown in Fig. 13a of that document.

Applicants direct the Examiner's attention to page 72, lines 7-8 of WO 97/27317 and to column 49, lines 1-4 of USP 6,344,316 for the following disclosure: "In addition, while Fig. 13a illustrates the probe oligonucleotide attached to a solid support by a 3' terminus, the probe can also be reversed and attached via the 5' terminus." Such an attachment would produce a free 3' overhang. Therefore, claims 5 and 16 are adequately supported by the priority documents.

Claims 11 and 18 are drawn to the method of claim 1 wherein the arrays are arranged in parallel. The Examiner, as stated in the § 103(a) rejection at page 11 of the Final Office Action is of the opinion that WO 97/27317 does not specifically disclose arrays arranged in parallel.

Applicants direct the Examiner's attention to page 31, lines 1-2 of WO 97/27317 and to column 20, lines 40-42 of USP 6,344,316 for the following disclosure: "the extremely large number of probes allows massively parallel processing of hybridizations." There are only a finite number of arrangements that would allow for parallel processing, all of which are subsumed within the disclosure at column 20, and one of which would be arrangement in parallel. Therefore, claims 11 and 18 are adequately supported by the priority documents. Applicants request withdrawal of the denial of § 120 priority.

§102(b) Rejection of the Claims

Claims 1-4, 6-10, 12-15, 17, and 19 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by International Publication WO 97/27317 to Lockhart et al. Applicants submit that in view of the amended claim of priority to International Publication WO 97/27317, this

document is not prior art. Applicants request withdrawal of this rejection under 35 U.S.C. § 102(b).

§102(e) Rejection of the Claims

Claims 1-4, 6-10, 12-15, and 17 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent 6,344,316 to Lockhart et al. Applicants submit that in view of the amended claim of priority to U.S. Patent 6,344,316 filed June 25, 1997, this document is not prior art. Applicants request withdrawal of this rejection under 35 U.S.C. § 102(e).

§103(a) Rejections of the Claims

1. Rejection over Lockhart et al. in view of Cantor

Claims 5 and 16 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over WO 97/27317 to Lockhart et al. in view of Cantor (U.S. 5,631,134).

Applicants submit that in view of the amended priority claim provided herein, and in view of the adequate support for these claims in the priority document, WO 97/27317 to Lockhart et al. is not prior art. Furthermore, the Examiner has acknowledged that Cantor alone does not render Applicants invention obvious, as evidenced by her combination rejection under § 103 of claims 1-19 over Cantor in view of Southern and Lipshutz et al. Applicants therefore request withdrawal of this rejection under 35 U.S.C. § 103(a).

2. Rejection over Lockhart et al. in view of Southern

Claims 11 and 18 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over WO 97/27317 to Lockhart et al. in view of Southern (U.S. 5,700,637).

Applicants submit that in view of the amended priority claim provided herein, and in view of the adequate support for these claims in the priority document, WO 97/27317 to Lockhart et al. is not prior art. Furthermore, the Examiner has acknowledged that Southern alone does not render Applicants invention obvious, as evidenced by her combination rejection under § 103 of claims 1-19 over Cantor in view of Southern and Lipshutz et al. Applicants therefore request withdrawal of this rejection under 35 U.S.C. § 103(a).

3. Rejection over Cantor et al. in view of Southern and Lipshutz et al.

Claims 1-19 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Cantor (U.S. 5,631,134, filed June 5, 1995) in view of Southern (U.S. 5,700,637, filed April 19, 1994) and Lipshutz et al (U.S. 6,300,063, filed November 29, 1995).

This rejection is respectfully traversed. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation either in the cited references themselves or in the knowledge generally available to an art worker, to modify the reference or to combine reference teachings so as to arrive at the claimed method. Second, the art must provide a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations (M.P.E.P. § 2143). The teaching or suggestion to arrive at the claimed method and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure (M.P.E.P. § 2143 citing with favor, *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

Applicants again submit that a *prima facie* case of obviousness cannot be established from the combination of cited documents because *inter alia* the documents neither teach nor suggest all the claim elements. In particular, the combination of documents fails to teach use of a complete set of n-mers and hybridization of a target and reference polynucleotides to two identical polynucleotide probe arrays, comparing intensity differences of probes in the reference and target hybridization patterns, and determining whether a mutation is present in the target polynucleotide.

The Examiner has cited *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981) and *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) in support of her position that "one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references." Final Office Action at page 19. Applicants urge that these decisions are inapposite.

Keller reiterates that the established test for combining reference teachings is "what the combined teachings of the references would have suggested to those of ordinary skill in the art." *Keller* at 642 F.2d 425 (citations omitted). In *Keller*, the Examiner had cited three references (Keller, Berkovits, and Walsh) in two combinations in a § 103 rejection of the claims. The appellant had submitted an affidavit that dealt only with what affiant thought Walsh suggested.

The court viewed this affidavit as “attacking references individually” because “[t]he affidavit does not indicate that Dr. Cywinski critically reviewed the use of digital timing in a cardiac pacer as prima facie established by the two combinations of references.” *Keller* at 642 F.2d 426 (emphasis added).

Therefore, the decision in *Keller* does not stand for the proposition that one cannot discuss the individual teachings of each reference used in a combination rejection under § 103. Actually, the court is saying precisely the opposite i.e., one cannot discuss only the teachings of one reference to the exclusion of the others used in the rejection. The only way to determine “what the combined teachings of the references would have suggested to those of ordinary skill in the art.” is to discuss the individual teachings of the references and then to discuss what the individual teachings would have suggested when combined. If elements of Applicants’ claims are absent from the individual references, combining those references will not result in Applicants’ invention.

Similarly, *Merck* does not stand for the proposition that one cannot discuss the individual teachings of each reference used in a combination rejection under § 103. The *Merck* court cited *Keller* for the “attacking references individually” position therein. *Merck* at 800 F.2d 1097. However, the *Merck* court went on to say that one reference “must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.” *Id.*(emphasis added). Appellant had argued that one reference in the combination rejection taught away from his invention. Therefore, it is clear that the *Keller* court meant attacking references *in isolation* when it used the phrase “attacking references individually”.

Applicants have not isolated one document and omitted discussion of others, as in the cited decisions. Instead, Applicants have described all of the cited documents in their argument that 1) when combined, all elements of Applicants invention are not present, and 2) the combination of documents would not suggest the missing elements so as to produce Applicants’ invention. In so doing, they have followed properly the *Keller* test of “what the combined teachings of the references would have suggested to those of ordinary skill in the art.”

Withdrawal of this rejection is respectfully requested.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney (703) 239-9592 to facilitate prosecution of this application.

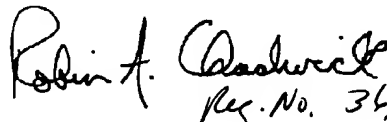
If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

KEVIN L. GUNDERSON ET AL.

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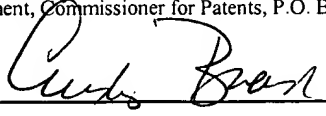
Date November 17, 2004 By _____

Richard A. Schwartz
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CERTIFICATE UNDER 37 CFR § 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelop addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of November 2004

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